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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
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09/693,121

10/20/2000

Jeffrey Schlom

45394

7805

50187

7590

06/06/2005

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|--------------------------------------|--|
| Office Action Summary | Application No. 09/693,121 | Applicant(s) SCHLOM ET AL. | |
| | Examiner Christopher H. Yaen | Art Unit 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-20 and 22-35 is/are pending in the application.
- 4a) Of the above claim(s) 23 and 32-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20, 22 and 24-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: Schlom *et al*

1. The amendment filed 3/14/2005 is acknowledged and entered into the record. Accordingly, claims 1-16, and 21 are canceled without prejudice or disclaimer, and claims 30-35 are newly added.
2. Claims 17-20 and 22-35 are pending, claims 23, and 32-33 are withdrawn from further consideration as being drawn to non-elected subject matter. Specifically, only claims drawn to the elected species of avipox are being examined on the merits (see action mailed 10/3/2002). Therefore, claims 20 and 31 are examined to the extent that is reads on the elected species of avipox and claim 25 is read to the extent that is reads on the elected species of RIBI.
3. The declaration by Dr. Schlom filed on 3/14/2005 is acknowledged.
4. Claims 17-20,22, and 24-31 are examined on the merits.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 102

6. The rejection of claims 17-19, 24-26, 28 and now newly added claim 35 under 35 USC § 102(e) as being anticipated by Spitler *et al* is maintained for the reasons of record. Applicant argues that Spitler *et al* do not teach the claimed invention. Specifically, applicant argues that Spitler *et al* do not teach a co-stimulatory molecules, or a method of generating a cytotoxic T-cell response. Applicant's arguments have

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been carefully considered but are not deemed persuasive to overcome the rejection of record.

The claims are drawn to a method comprising the administration of a sufficient amount of PSA or alternatively a cytotoxic T-cell epitope thereof and a cytokine or alternatively a co-stimulatory molecule. Spiliter *et al* teach a method of administering PSA and a cytokine. Because the claimed limitation of "co-stimulatory molecule" is claimed in the alternative, the claim has been interpreted using the alternative (i.e. a cytokine). Moreover, in response to applicant's arguments concerning the lack of teaching a "critical element" of the claim, the recitation of generating a cytotoxic T-cell eliciting immune response has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Applicant additionally contends that Spiliter *et al* does not enable the skilled artisan to practice an invention commensurate in scope to the present claims. Specifically, applicant argues by presenting a declaration by Dr. Schlom to support their assertions. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. The declaration of Dr. Schlom is

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acknowledged. All US Patents are presumed to be valid. The examiner will not comment on the validity of another US Patent.

Therefore the rejection of claims under 35 USC§ 102 is maintained for the reasons of record.

Claim Rejections Maintained - 35 USC § 103

7. The rejection of claims 17-20,22,24-29 and now claims 30-31 and 35 under 35 USC § 103(a) as being obvious over Spitler *et al* in view of Fields and Hodge *et al* is maintained for the reasons of record. Applicant argues that the Spiltler *et al* does not constitute prior art because the cited reference does not teach every limitation of the claim. These arguments have been addressed, *supra* (see paragraph 6).

Applicant additionally argues that Fields (*Fields Virology 3rd Ed. Vol 2*. Lippincot, Williams, and Wilkins, pages 2637-2671, herein Fields `96) was published in 1996 which is after the filing date of the continuation application 08/500,306 (now US Patent 6,165,460), from which the instant application claims priority. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. Although the applicant is correct in the publication date of the Fields `96, the rejection is still maintained because the information supplied in the Fields `96 is identical to that supplied in an earlier edition. Therefore, the claim is newly rejected under Fields *et al* (*Fundamental Virology 2nd Ed.* Raven Press 1991, pages 953-973, herein Fields `91). Moreover, Fields `91 provides general disclosure of pox viruses and

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further provides the motivation of using pox viruses for gene transfer (see in particular page 973).

Applicant also argues that Hodge *et al* is not prior art because they do not teach the use of PSA. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In *re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In *re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, Hodge *et al* is used in combination with both Spitler *et al* and in view of Fields '91 (newly cited). Therefore, the argument presented by the applicant is not deemed persuasive.

Applicant also contends that they possessed the invention prior to Spitler *et al*. Applicant supports this contention by providing a Declaration filed under 37 CFR 1.131 by both Schlom and Panicali. Applicant's declaration is acknowledged but is not deemed persuasive to overcome the rejection of record because the declaration has not been signed by both inventors of the application, and is therefore defective. Affidavits or declarations to overcome a rejection of a claim or claims must be made by the inventor or inventors of the subject matter of the rejected claim(s), a party qualified under 37 CFR 1.42, 1.43, or 1.47, or the assignee or other party in interest when it is not possible to produce the affidavit or declaration of the inventor(s). Thus, where all of the named inventors of a pending application are not inventors of every claim of the application, any affidavit under 37 CFR 1.131 could be signed by only the inventor(s) of

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the subject matter of the rejected claims. Further, where it is shown that a joint inventor is deceased, refuses to sign, or is otherwise unavailable, the signatures of the remaining joint inventors are sufficient. However, the affidavit or declaration, even though signed by fewer than all the joint inventors, must show completion of the invention by all of the joint inventors of the subject matter of the claim(s) under rejection. In re Carlson, 79 F.2d 900, 27 USPQ 400 (CCPA 1935). In the instant case, the applicant has not made an indication as to why both inventors have not signed the declaration.

Therefore, the rejection of claims under 35 USC 103 (a) as being obvious is maintained for the reasons of record.

Conclusion

No claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
May 17, 2005


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
5/31/05